UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Risk Assessment for a FIFRA Section 3 Registration of a Manufacturing Use Product (Homeplate MUP) and an End Use Products (Homeplate RTU), Containing 2.62% Caprylic Acid and 2.17% Capric Acid as its Active Ingredient.

Decision Number:	553040
DP Number:	453472
Submission Number:	1037184
EPA File Symbol Number:	67702-LI, LO
Active Ingredient Type:	Biochemical
PC Code:	128919; 128955
CAS Number:	124-07-02; 334-48-5
Active Ingredient Tolerance/Exemption:	40 CFR 180.940 (c)
MRID Numbers:	50359607; 50359616; 50359617; 50979501-04; 50886401-04; 50886501-06
PRIA Code:	B673

FROM: W. Baylor Steele, Biologist
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

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THROUGH: Russell Jones, Ph.D., Senior Scientist
Shannon Borges, Branch Chief
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TO: Anna, O'Neil, Risk Manager
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

On behalf of Neudorff GmbH KG, W. Talarek requests registration of a technical grade active ingredient/manufacturing use product (TGAI/MP) and an end-use product (EP) containing caprylic and capric acid, intended for use to control broadleaf weeds, grass, algae and moss on vegetable and flower gardens, landscaped areas, and in the vicinity of small fruits, vines and fruit trees. The EP is also intended for use around and on buildings, sidewalks, fences, bark mulch, driveways, patios and gravel. In support of the registration, the applicant submitted a proposed product label, Confidential Statements of Formula (CSFs) dated 07-03-2019, 11-01-19, and 11-07-19, data matrices dated 07-03-2019, 07-25-

19, and 11-06-19, product chemistry data, and human health assessment data.

EXECUTIVE SUMMARY

Neudorff GmbH KG is requesting registration of a TGAI/MP (Homeplate MUP, 36.67% caprylic acid and 30.00% capric acid) from unregistered sources and an EP (Homeplate RTU) containing caprylic acid at 2.62% and capric acid at 2.17%. Caprylic and capric acid are medium chain fatty acids (MCTs) of eight and ten carbon atoms in length, respectively. The biochemicals are intended for use as herbicides and have been registered for use as pesticides since 1994. Both of the active ingredients are completely biodegradable and found extensively in nature. Specifically, these substances occur in a number of plant and animal sources such as animal oils, fats, butter, coconut oil, etc.

The Agency has reviewed and evaluated the product chemistry and human health data for the proposed MP and EPs. All data requirements have been met, and no risks of concern have been identified for the biopesticide products when used in accordance with label instructions.

1. Biopesticide Use Pattern

Homeplate RTU is a liquid formulation intended for use to control broadleaf weeds, grass, algae and moss on vegetable and flower gardens, landscaped areas, and in the vicinity of small fruits, vines and fruit trees. The active ingredients are also intended for use around and on buildings, sidewalks, fences, bark mulch, driveways, patios and gravel. The product is applied as a spray using a portable hand-held sprayer so that the plant, including the center/stem, is thoroughly covered with the formulation. Applications can be made at two to three-week intervals.

2. Product Chemistry

A. Active Ingredient

All product chemistry data requirements have been satisfied for the MP and the active ingredients. The applicant submitted acceptable information for each of the chemistry data requirements. These data were used to create a Data Evaluation Record (DER) that is included as a separate attachment from this memorandum. The active ingredient product chemistry and physical/chemical properties are summarized in Tables 1, 2, 3 and 4.

B. End-Use Product

All product chemistry data requirements have been satisfied for the proposed product. To satisfy these requirements, the applicant submitted acceptable studies for each of the chemistry data requirements. The product chemistry data are summarized in Table 1. Physical and chemical properties of the EP are provided in Table 4. Refer to the attached Data Evaluation Record (DER) for additional information.

TABLE 1. Product Chemistry Data for Homeplate MUP and Homeplate RTU (40 CFR § 158.2030)			
OSCPP Guideline	**Study**	**Results**	**MRID**
880.1100 830.1550	Product identity and composition	The product identity and composition were adequately addressed. ACCEPTABLE	50886401 50886402 50886501 50886502
880.1200 830.1650	Description of starting materials and formulation process	Submitted data satisfy the requirements for the description of the starting materials, production, and formulation process. ACCEPTABLE	50886401 50886402 50886501 50886502
880.1400 830.1670	Discussion of formation of impurities	Submitted data satisfy the requirements for discussion of formation of impurities. ACCEPTABLE	50886401 50886402 50886501 50886502
830.1700	Preliminary analysis	Submitted data satisfy the requirements for analysis of samples ACCEPTABLE	50886401 50886402 50886501 50886502
830.1750	Certified limits	Submitted data satisfy the requirements for certified limits ACCEPTABLE	50886401 50886402 50886501 50886502
830.1800	Enforcement analytical method	Submitted data satisfy the requirements for enforcement analytical method ACCEPTABLE	50886401 50886402 50886501 50886502

TABLE 2. Physical and Chemical Properties of Caprylic acid (40 CFR § 158.2030)			
OCSPP Guideline	**Property**	**Description of Result**	**MRID**
830.6302	Color	Colorless	50359616
830.6303	Physical State	Oily liquid	50359616
830.6304	Odor	Faint, fruity-acid odor	50359616
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Stable; Product is not expected to come into contact with metal or metal ions during storage.	50886403
830.6315	Flammability	Flash Point: 130 °C	50359616
830.6317	Storage Stability	Stable	50979501
830.6319	Miscibility	Not applicable; substance is not an emulsifiable liquid and is not diluted with petroleum solvents	-
830.6320	Corrosion Characteristics	Not Corrosive	50979501
830.7000	pH	3.16	50359607
830.7050	UV/Visible Light Absorption	Neutral: Peak not found; Basic: 213-227 nm; Acidic: Peak not found	50359616
830.7100	Viscosity	Not Required for TGAI	-
830.7200	Melting Point/Range	Not applicable; substance is a liquid	-
830.7220	Boiling Point/Range	239 °C	50359616
830.7300	Density	0.910 g/mL @ 20.0 °C	50359616
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not applicable; substance is a liquid	-
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Log Pow = 3.05	50359616
830.7840	Water Solubility	789 mg/L	50359616
830.7950	Vapor Pressure	3.7×10^{-3} mm Hg at 25 °C	50359616

TABLE 3. Physical and Chemical Properties of Capric Acid (40 CFR § 158.2030)			
OCSPP Guideline	**Property**	**Description of Result**	**MRID**
830.6302	Color	White	50359617
830.6303	Physical State	Crystalline Solid	50359617
830.6304	Odor	Rancid Odor	50359617
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Stable; Product is not expected to come into contact with metal or metal ions during storage.	50886403
830.6315	Flammability	Flash Point: 112 °C	50979504
830.6317	Storage Stability	Stable	50979501
830.6319	Miscibility	Not applicable; substance is not an emulsifiable liquid and is not diluted with petroleum solvents	-
830.6320	Corrosion Characteristics	Not Corrosive	50979501
830.7000	pH	3.16	50359607
830.7050	UV/Visible Light Absorption	Neutral: Peak not found; Basic: 213-227 nm; Acidic: Peak not found	50359607
830.7100	Viscosity	Not Required for TGAI	-
830.7200	Melting Point/Range	31.5 °C	50359617
830.7220	Boiling Point/Range	Not applicable; substance is a solid	-
830.7300	Density	0.890 g/mL @ 40.0 °C	50359617
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not applicable	-
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Log Pow = 4.09	50359617
830.7840	Water Solubility	15 mg/L	50359617
830.7950	Vapor Pressure	3.66×10^{-3} mm Hg at 25 °C	50359617

TABLE 4. Physical and Chemical Properties of Homeplate RTU (40 CFR § 158.2030)			
OCSPP Guideline	**Property**	**Description of Result**	**MRID**
830.6302	Color	Hue of R-Y, Value of 9, and Chroma of 10YR	50886503
830.6303	Physical State	Liquid	50886503
830.6304	Odor	Very faint sweet odor	50886503
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Not required for EP	-
830.6315	Flammability	Not flammable	50886503
830.6317	Storage Stability	Stable when stored for 2 weeks at 54°C	50886503
830.6319	Miscibility	Not applicable; substance is not an emulsifiable liquid and is not diluted with petroleum solvents	50886503
830.6320	Corrosion Characteristics	Non-corrosive when stored for 2 weeks at 54°C	50886503
830.7000	pH	4.01 ± 0.85	50886503
830.7050	UV/Visible Light Absorption	Not required for EP	-
830.7100	Viscosity	60 ± 54 cPs @ 12 RPM	50886503
830.7200	Melting Point/Range	Not required for EP	50886503
830.7220	Boiling Point/Range	Not required for EP	50886503
830.7300	Density	1.01 ± 0.01g/ml at 20°C	50886503
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not required for EP	-
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Not required for EP	-
830.7840	Water Solubility	Not required for EP	-
830.7950	Vapor Pressure	Not required for EP	-

3. Human Health Risk Assessment

A. Active Ingredient

Tier 1 toxicity data (acute toxicity, subchronic toxicity, developmental toxicity and genotoxicity) are required for TGAIs. To satisfy these data requirements for capric and caprylic acid, the applicant requested to bridge toxicity data from old (>15 years) guideline studies with pelargonic acid, an MCT with nine carbon atoms. Based on the structural similarities among MCTs, toxicity data can be used almost interchangeably as surrogate data for these three substances (US EPA 2008; US EPA 2019a). The pelargonic acid studies cited by the applicant have been previously reviewed and accepted by the Agency (US EPA 2010). Therefore, all human health assessment data requirements have been satisfied and a new risk assessment for the active ingredients is not required at this time. BPPD's current risk assessments are sufficient to evaluate the use of this active ingredient in the proposed product because the use pattern of this product is similar to that of currently registered products. No risks of concern have been identified.

B. Manufacturing-Use and End-Use Products

Acute toxicity data (acute oral, acute dermal, acute inhalation, primary eye, primary dermal and skin sensitization) are required for EPs. To satisfy all acute toxicity data requirements for the MP and oral, dermal, and inhalation requirements for the EP, the applicant requested to bridge toxicity data from a previously registered product, Fireworxx 80 (EPA Symbol #: 67702-54). Fireworxx 80 contains caprylic (43.74%) and capric (36.17%) acid at higher levels than the MP and EP currently under registration. Furthermore, the inert ingredients in Homeplate RTU and Homeplate MUP are not expected to be of greater toxicity than the inert ingredient contained in Fireworxx 80. Therefore, toxicity values of Fireworxx 80 can be expected to be protective of Homeplate MUP (MP) and Homeplate RTU (EP). The applicant submitted guideline studies to satisfy eye irritation, dermal irritation, and skin sensitization data requirements for the EP (Homeplate RTU). The toxicity studies for Fireworxx 80 have been previously reviewed and considered acceptable by the Agency (US EPA 2019b). Summaries of the EP toxicity data are provided in Table 5.

TABLE 5. Human Health Assessment Data for Homeplate MUP (40 CFR § 158.2050)

OCSPP Guideline No.	Results	Toxicity Category/ Description	MRID
Acute oral toxicity* (870.1100)	LD_{50} > 5,000 mg/kg ACCEPTABLE/GUIDELINE	IV	50359610
Acute dermal toxicity* (870.1200)	LD_{50} > 5,050 mg/kg ACCEPTABLE/GUIDELINE	IV	50359611
Acute inhalation toxicity* (870.1300)	LC_{50} > 5.22 mg/L ACCEPTABLE/GUIDELINE	IV	50359612
Primary eye irritation (870.2400)	Mildly irritating ACCEPTABLE/GUIDELINE	III	50886504
Primary dermal irritation (870.2500)	Slightly irritating ACCEPTABLE/GUIDELINE	IV	50886505
Dermal sensitization (870.2600)	Not a sensitizer	-	50904901

LD_{50} = median lethal dose; LC_{50} = median lethal concentration
*Toxicity data bridged from studies with Fireworxx 80, containing 43.74% caprylic acid and 36.17% capric acid

4. Nontarget Organism Risk Assessment

A. Active Ingredient

Tier 1 nontarget organism toxicity data (avian, fish, aquatic invertebrates, plants and nontarget insect toxicity) are required for TGAI/MPs. To satisfy data requirements for avian, fish, aquatic invertebrate, and insect toxicity, the applicant requested to bridge toxicity data from old (>15 years) guideline studies with pelargonic acid. The pelargonic acid studies cited by the applicant have been previously reviewed and accepted by the Agency (US EPA 2014; US EPA 2019a).

For nontarget plant toxicity data requirements, the applicant cites rationale previously used for EPA ecological hazard assessments. These assessments state that fatty acids normally are metabolized, forming simple compounds that serve as energy sources and structural components used in all living

cells (US EPA 2009). Furthermore, these compounds are ubiquitous in nature and undergo rapid breakdown in the environment. Lastly, when used as pesticides, fatty acids kill weeds through a physical (i.e. stripping of the plant cuticle and desiccation), non-toxic mode of action. Leaves of undesirable vegetation must be uniformly sprayed and thoroughly wetted to the point of saturation for the active ingredients to be effective. Exposure to non-target plants through spray drift is not anticipated to thoroughly saturate surfaces necessary for herbicidal activity to occur and any adverse effects to non-target plants such as localized desiccation would not be permanent (US EPA 2019a).

All nontarget organism toxicity data requirements have been satisfied and a new risk assessment for caprylic and capric acid is not required at this time. BPPD's current risk assessments are sufficient to evaluate the use of this active ingredient in the proposed product because the use pattern of this product is similar to that of currently registered products. No risks of concern have been identified. Summaries of the nontarget organism toxicity data for the TGAIs are provided in Table 5.

TABLE 5. Nontarget Organism Toxicity Profile for Caprylic and Capric Acid (40 CFR § 158.2060)

Study/OCSPP Guideline No.	Results[1]	Toxicity Category/Description	MRID
Avian acute oral toxicity (850.2100)	LD_{50} > 2250 mg/kg ACCEPTABLE/GUIDELINE	Practically Nontoxic	49222214
Freshwater fish acute toxicity (850.1075)	LC_{50} = 91 mg/L ACCEPTABLE/GUIDELINE	Slightly toxic	43065302
Aquatic invertebrate acute toxicity (850.1010)	EC_{50} = 96 mg/L ACCEPTABLE/GUIDELINE	Slightly toxic	43065303
Nontarget insect testing (880.4350)	LD_{50} >25µg/bee ACCEPTABLE/GUIDELINE	Practically non-toxic	43052401

LD_{50} = median lethal dose; EC_{50} = median estimated concentration.

B. End-Use Product

Nontarget organism data are typically not required for biochemical pesticide products, unless triggered based on a concern for toxicity from an inert ingredient.

These data requirements have not been triggered at this time for the proposed product and as stated previously, BPPD's current risk assessments are sufficient to evaluate the use of the proposed product. No risks of concern have been identified.

5. Product Performance

Product performance data are not required to be submitted to the Agency at this time because there are no claims to control public health pests on the proposed product label.

RECOMMENDATIONS AND CONCLUSIONS

1. All product chemistry data submitted for the MP and EP application are ACCEPTABLE.

2. In the discussion of formulation process (OCSPP 880.1200) and the certified limits (OCSPP 830.1750), alternate formulation numbers 1-7 are all included. However, formulations 1,2,4, and 7 are the only formulations that have been approved as alternate formulations. Discussion of the unapproved formulations need to be removed from the MRIDs (MRIDs 50886501 and 50886502).

2. The submitted basic CSFs for the MP (EPA File Symbol: 67702-LI) and EP (EPA File Symbol: 67702-LO) dated 07-03-2019, 11-01-19, and 11-07-19 are ACCEPTABLE.

3. The cited studies in support of the MP application for acute human health toxicity are ACCEPTABLE. Toxicity data for the MP were bridged from studies with an older product, Fireworxx 80, containing 43.74% caprylic acid and 36.17% capric acid. Toxicity data for the TGAIs were satisfied through bridging data from old (>15 years) guideline studies with pelargonic acid, an MCT with nine carbon atoms. The cited toxicity data for the MP and TGAIs has been previously reviewed and considered acceptable by the Agency (US EPA 2010; US EPA 2019b).

4. The cited studies in support of the EP applications for acute human health toxicity are ACCEPTABLE. The EP, Homeplate RTU, can be classified as Category IV for acute oral, acute dermal, acute inhalation, and primary dermal irritation. The product can be classified as Category III for primary eye irritation.

5. The cited studies in support of the MP application for non-target organism toxicity are ACCEPTABLE. To satisfy data requirements for the non-target organism toxicity of the TGAIs, the applicant requested to bridge toxicity data from old (>15 years) guideline studies with pelargonic acid. The pelargonic acid studies cited by the applicant have been previously reviewed and accepted by the Agency (US EPA 2014; US EPA 2019a).

6. No risks of concern are expected to occur for the proposed EP and MP.

BIBLIOGRAPHY OF STUDIES

MRID 50359607: ACCEPTABLE

MRID 50359616: ACCEPTABLE

MRID 50359617: ACCEPTABLE

MRIDs 50979501-04: ACCEPTABLE

MRIDs 50886401-04: ACCEPTABLE

MRIDs 50886501-06: ACCEPTABLE

REFERENCES

US EPA. 2008. Caprylic (Octanoic) Acid Registration Review, Dated June 2008.

US EPA. 2009. Capric (Decanoic) Acid Final Registration Review Decision, Registration Review Case 5038, Dated March 2009.

US EPA. 2010. Memorandum. Preliminary Human Health Assessment for the Registration Review of Pelargonic Acid. By Colin G. Walsh, Biologist. Signed May 17, 2010

US EPA. 2014. Memorandum. Application for registration of Neudorffs Granular Moss Killer. By Miachel Rexrode, Ph.D., Senior Biologist. Signed June 23, 2014

US EPA. 2019a. Memorandum. Registration Review Draft Risk Assessment for Pelargonic Acid, Salts, and Esters, Dated September 2019.

US EPA. 2019b. Label Amendment (B683) for Fireworxx 80 (EPA Symbol #: 67702-54), Containing 36% of Capric Acid & 44% of Caprylic Acid. Review of CSF, Label, Product Chemistry and Toxicity. By Manying Xue, Chemist. Dated September 5, 2019

cc: Baylor Steele, Angela Gonzales, Anna, O'Neil, BPPD, Documentum
Baylor Steele, Biologist, FT, PY-S: March 09, 2020